

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Selective internal radiation therapy for unresectable colorectal metastases in the liver

Bowel cancer that has spread to other parts of the body is called colorectal metastases. In the liver this can be unresectable (can't be removed using surgery). In this procedure tiny radioactive 'beads' are injected into blood vessels supplying the colorectal metastases, where they become trapped. The beads release radiation directly into the cancer cells. The aim is to destroy the cancer cells while causing as little damage to the liver as possible.

This is a review of NICE's interventional procedures guidance on [selective internal radiation therapy for non-resectable colorectal metastases in the liver](#).

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for [consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution](#) process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 August 2019

Target date for publication of guidance: November 2019

## 1 Draft recommendations

1.1 Evidence on the safety of selective internal radiation therapy (SIRT) for unresectable colorectal metastases in the liver shows there are well-recognised and potentially serious safety concerns.

- In people who cannot tolerate chemotherapy or have liver metastases that are refractory to chemotherapy, there is evidence of efficacy but this is limited, particularly for important outcomes such as quality of life. Therefore, in these people, this procedure should only be used with [special arrangements](#) for clinical governance, consent, and audit or research.
- In people who can have chemotherapy, evidence on efficacy does not show a benefit on overall survival or quality of life. Therefore, in these people, this procedure should only be used in the context of [research](#).

1.2 Clinicians wishing to do SIRT for unresectable colorectal metastases in the liver, in people who cannot have chemotherapy or have liver metastases that are refractory to chemotherapy, should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear written information to support [shared decision making](#), including NICE's [information for the public](#).
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. Clinicians should enter details for all patients having SIRT for unresectable colorectal metastases in the liver onto a suitable register and review clinical outcomes locally.

- 1.3 Patient selection should be done by a specialist hepatobiliary cancer multidisciplinary team that can offer the full range of treatment options for this condition.
- 1.4 This procedure should only be done by clinicians with specific training in SIRT including techniques to minimise the risk of damage to surrounding tissue.
- 1.5 Further research should report details of patient selection, whether the primary colorectal tumour arose in the left or right side of the colon, extrahepatic disease, and tumour-to-liver volume. Outcomes should include survival and quality of life.
- 1.6 NICE may update the guidance on publication of further evidence.

## **2 The condition, current treatments and procedure**

### ***The condition***

- 2.1 Around 30% to 50% of people with colorectal cancer have liver metastases at the time of presentation or develop them during the course of the disease.

## ***Current treatments***

- 2.1 Treatment of liver (hepatic) metastases depends on their extent and location. For unresectable tumours, treatment options include thermal ablation techniques, chemotherapy, different types of arterial embolisation therapy and external beam radiotherapy.

## ***The procedure***

- 2.2 Selective internal radiation therapy (SIRT; also known as radioembolisation) can be used as palliative treatment for unresectable colorectal metastases in the liver. It may also be used as a neoadjuvant treatment in patients being considered for curative treatments such as resection or liver transplantation.
- 2.3 SIRT involves delivering microspheres containing radionuclides that emit beta radiation directly into the tumour. This aims to minimise the risk of radiation damage to surrounding healthy tissue. Using local anaesthesia and fluoroscopic guidance, the radioactive microspheres are injected into branches of the hepatic artery supplying the tumour. A percutaneous approach is used through the femoral or radial artery. The microspheres lodge in small arteries within and surrounding the tumour, releasing high doses of radiation directly into it. The procedure may be repeated depending on the response.

## **3 Committee considerations**

### ***The evidence***

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 3 publications from 4 randomised controlled trials (3 were analysed together in a single report and 2 of these 3 were also

used for a post-hoc analysis, reported in a single study), 2 non-randomised comparative studies and 3 case series. It is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, survival and reduction in tumour volume.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: hepatic toxicity, abdominal pain and haematological toxicity.

### ***Committee comments***

3.4 The committee was advised that the benefit is greater for patients with limited extrahepatic disease and tumour-to-liver volumes below 25%.

3.5 The committee noted that different types of microspheres and radionuclides are used.

3.6 The committee noted that many studies did not report quality of life and it considers this to be an important outcome.

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Chair, interventional procedures advisory committee

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